

Notice of Allowability

Application No.

09/830,144

Applicant(s)

TSUCHIYA ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to Amdt and RCE of October 7, 2004.

☒ The allowed claim(s) is/are 68-87.

☒ The drawings filed on 07 February 2002 are accepted by the Examiner.

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1004

☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.

DETAILED ACTION

Applicant's response and Request for Continuing Examination, received October 7, 2004, to the Final Rejection of this case, mailed December 15, 2003, is acknowledged. It is acknowledged that applicants have cancelled Claims 1-67 and added Claims 68-87. Claims 68-87 are pending and are hereby considered.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Specification

On page 52, line 31 replace $IL-1\alpha$ with $IL-1\beta$.

Claims

For Claim 68, replace line 1-2 with: A method of screening for compounds that inhibit production of an inflammatory cytokine, comprising:—.

For Claim 68, insert the following at the end: —, wherein the compound inhibits production of an inflammatory cytokine produced in response to lipopolysaccharide (LPS) or $IL-1\alpha$.

Authorization for this examiner's amendment was given in a telephone interview with Janis Fraser's representative, Ping Hwung, on December 21, 2004.

Allowable Subject Matter

Claims 68-87 are allowed.

The following is an examiner's statement of reasons for allowance:

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Claims 2-11, 27, 41, 42, and 54-59 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Shibuya et al, 1996 in view of McCartney-Francis et al, 1998, Letterio et al, 1998, and Maeda et al, 1995. Claims 43-53 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Shibuya et al, 1996 in view of McCartney-Francis et al, 1998, Letterio et al, 1998, and Maeda et al, 1995 and further in view of Wells et al, 1996. Said rejections are withdrawn because Claims 2-11, 27, and 41-59 have been cancelled. Furthermore, said rejections are not relevant to Claims 68-87 for the following reasons. As stated in the Final Rejection, mailed December 13, 2003, it is known in the art that TAK1/TAB1 binding mediates the action of TGF- β and that TGF- β stimulates the production of the inflammatory cytokines IL-1, IL-6, TNF, and IL-10. Therefore, it would have been obvious to test any compound that inhibits TAK1/TAB1 binding for inhibition of TGF- β -induced expression of IL-1, IL-6, IL-10, and TNF, thus rendering the invention of Claims 2-11, 27, and 41-59 obvious. However, Claim 68, as amended, recites a method of screening for compounds that inhibit the production of inflammatory cytokines that are produced in response to IL-1 α or LPS. None of Shibuya et al, 1996, McCartney-Francis et al, 1998, Letterio et al, 1998, Maeda et al, 1995, or Wells et al, 1996 teach that TAB1/TAK1 mediates LPS- or IL-1 α -induced cytokine production. In fact, the ability of TAB1/TAK1 to mediate LPS- or IL-1 α -induced cytokine production was not known in the art prior to the filing date of the instant application. Therefore, the instant invention is non-obvious over the prior art.

All elected Claims, 68-87, are limited to a method of screening for modulators of inflammatory cytokine production by testing compounds for inhibition of binding between TAK1 and TAB1. The utility of said method is based on the following. The prior art teaches that TAB1 mediates activation of TAK1 in response to TGF- β (Shibuya et al, 1996). The instant

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application teaches that over-expression of a dominant negative construct of TAK1, having the TAB1 binding site, inhibits production of inflammatory cytokines in response to LPS and IL-1 α (Figs 4 and 5). Therefore, one of skill in the art would believe that an assay testing for inhibitors of binding between TAK1 and TAB1 would be useful as a means to screen for compounds that inhibit the production of inflammatory cytokines in response to LPS and IL-1 α .


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan L. Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800-
1600